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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,685

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Einar Mocn

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EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

1657

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,685

Applicant(s)

MOEN ET AL.

Examiner

Satyendra K. Singh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response and amendment to claims filed with the office on August 3rd 2006 is duly acknowledged.

Claims 1-10 and 15-24 are cancelled by applicant's amendments to the claims.

Claims 11-14, 25-27, and newly added claims 28-34 are pending in the application, and are being examined on their merits, herein.

The following is a **new ground of rejection** necessitated by applicant's amendments to the pending claims.

Claims Suggestions

Claims 28 and 29 (newly added) recite the name of various **bacterial species** that are used in the claimed invention, in which the names (i.e. genus and species; for example, *Methylococcus capsulatus*) are **not italicized**. Applicants are requested to italicize the recitation of the scientific names for biological organisms used in the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 29 (newly added) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most connected, to make and/or use the invention.

The invention appears to employ novel biological material, bacterial strains (such as recited in instant claims 28 and 29). Since the biological materials (i.e. the claimed bacterial strains) are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological material is not so obtainable or available, the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the biological material. The specification does not disclose a repeatable process to obtain the biological material and it is not apparent if the biological material is readily available to the public.

It is noted that applicant has deposited the biological material (instant specification, page no. 3, second, full paragraph, in particular; and applicant's remarks filed on August 3rd 2006, page 6, last paragraph, in particular), but there is no indication in the specification as to **whether the deposit was made under Budapest treaty**. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological material (in the instant case, bacterial strains as recited in the instant claims 28 and 29) has been deposited under the Budapest Treaty and that the biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809, applicant may provide assurance of compliance by an

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affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. §1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and **address of the depository**, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification should be amended to include this information, however, applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 29 (newly added) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites "wherein said at least one species of heterotrophic bacteria **includes** *Ralstonia* sp. DB3 (strain NCIMB 13287), *Aneurinibacillus* sp. DB4 (strain NCIMB 13288), and *Brevibacillus agri* DB5 (strain NCIMB 13289)" which is an **improper language for a Markush claim** (see MPEP, chapter 2100 "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925"). The invention as claimed, is indefinite as it is not clear as to what is encompassed (scope of the invention) by the instant claim. It is not clear whether all the bacterial species recited in the claim have to be present together, or in various combinations, or one bacterial species at a time. Examiner suggests that the language of claim 29 be appropriately corrected to be in the proper form in order to be examined. The instant claim is being interpreted as a Markush claim for the examination purposes, herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-14, and 25-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Bothe et al (*Appl. Microbiol. Biotechnol.*, 2002; IDS) as evidenced by Norferm, DA (Product brochure, 1998; IDS) and Larsen & Joergensen (*Appl. Microbiol. Biotechnol.*, 1996; IDS).

Claims are generally directed to a **microorganism growth substrate** (i.e. a product) comprising: (a) a sterilized nutrient composition, wherein said composition is a **biomass generated from bacterial cells**, wherein the bacterial cells comprise at least one species of **methanotrophic** bacteria and at least one species of **heterotrophic** bacteria, (b) at least one **sterile nutrient** added to the biomass, and (c) optionally a **diluent** (see specific recitations of the broader claim 11 as amended currently).

Bothe et al (IDS) disclose a composition (i.e. a bacterial biomass) comprising biomass generated from bacterial cells, wherein bacterial cells comprising at least one species of methanotrophic bacteria (such as *M. capsulatus* (Bath) NCIMB 11132) (see Bothe et al, abstract, page 34, materials & methods, in particular) and at least one species of heterotrophic bacteria (such as *Ralstonia* sp., *Aneurinibacillus* sp., or *Brevibacillus* sp; see Bothe et al, abstract, pages 34, 35 and 38, in particular), at least one sterile nutrient (such as components of nitrate/mineral salts, NMS medium as described by Larsen & Joergensen; cited on page 138, left column, in particular).

The limitations of claims 12 and 25 (see Bothe et al, page 34, materials & methods), claims 28 and 29 (see Bothe et al, abstract, pages 34, 36-38, in particular), and claims 30-34 (see the disclosure of Norferm, DA as evidence, and Bothe et al, page 34, left column, in particular) are anticipated by the referenced invention of Bothe et al as evidenced by the disclosures provided by Norferm, DA and Larsen & Joergensen.

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Claims 13, 14, 26, and 27 are included in the rejections as they depend from the broader claim 12, and are being interpreted to encompass "at least one sterile nutrient added to the biomass" such as nitrate, mineral salts, or combinations thereof as disclosed in the referenced invention of Bothe et al (as supported by the disclosure in Larsen & Joergensen; see materials & methods, and discussion supra).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-14 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bothe et al (*Appl. Microbiol. Biotechnol.*, 2002; IDS), Norferm, DA (Product brochure, 1998; IDS), and Larsen & Joergensen (*Appl. Microbiol. Biotechnol.*, 1996; IDS) in view of Atlas & Parks (Handbook of Microbiological Media, 1993 edition; [U]).

Claims (13-14 and 26-27 as amended) are directed to a microorganism growth substrate composition wherein the **glucose** is present in a weight ratio of 5:1 to 1:5, on a dry mass basis relative to the biomass; wherein **nitrate and mineral salts** are present in a weight ratio of 0.01:1 to 0.2:1, relative to the biomass; the growth substrate as claimed in claim 13, wherein glucose is present in a weight ratio of 2:1 to 1:2, on a dry mass basis relative to the biomass; and the substrate as claimed in claim 14, wherein the nitrate and mineral salts are present in a weight ratio of 0.05:1 to 0.1:1, relative to the biomass.

The teachings of Bothe et al (in view of the disclosures from Norferm, DA and Larsen & Joergensen) have been discussed above, and are further relied upon in the same manner.

However, a microorganism growth substrate comprising a sterilized nutrient composition as specifically recited in claim 11, comprising at least one **sterile nutrient** added to the biomass, such as **glucose**, or a combination of nitrate and mineral salts that is present in a **weight ratio on a dry mass basis** (as specifically recited in instant claims 13, 14, 26 and 27), is not explicitly disclosed by the combined disclosures of Bothe et al (in view of the disclosures provided from Norferm, DA and Larsen & Joergensen).

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Atlas & Parks [U] provides the detailed disclosure about various nutrient media compositions routinely used for the cultivation (on solid as well as liquid media) of methanotrophic and heterotrophic bacteria (see Atlas & parks, for various methanotrophic bacteria, pages 574-579; and for heterotrophs such as various lactic acid bacteria and *Lactobacillus* spp., pages 483-488, in particular). Atlas & Parks teaches the use of glucose as a sterile nutrient for use in various media compositions routinely used for cultivation of various microbial species (see Atlas & Parks, pages 576, 483-488, in particular), and also the use of nitrate and mineral salts (see Atlas & Parks, pages 574-575, in particular) in the cultivation of microorganisms (being especially useful in the cultivation of methanotrophic bacteria).

It would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the microorganism growth substrate composition of (see also discussion, supra) Bothe et al (as supported by the disclosures of Norferm, DA and Larsen & Joergensen) such that the growth substrate comprises a sterile nutrient such as glucose, nitrate and mineral salts, and combinations thereof as explicitly taught by Atlas & parks [U]. The person of ordinary skill would be motivated to modify the growth substrate composition comprising the biomass generated from bacterial cultures (as taught by Bothe et al) because the sterile nutrient compositions containing glucose, nitrate and mineral salts have been routinely used in the cultivation of various microorganisms (methanotrophic as well as heterotrophic) as explicitly disclosed by Atlas & parks (see discussion, supra). One of ordinary skill in the art would have had a reasonable expectation of success when modifying the composition according to the

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disclosures of Atlas & Parks because Atlas & parks have explicitly taught the amounts, ratios and preparation of such growth media compositions that are useful in cultivation of various microorganisms.

Although, Atlas & Parks [U] do not explicitly teach a microorganism growth substrate composition wherein the sterile nutrient such as glucose, or a combination of nitrate and mineral salts are present in specific **dry mass basis** (as recited in the instant claims 13, 14, 26 and 27) in relation to the biomass (obtained from the culture of methanotrophic and heterotrophic bacteria) used in the invention as claimed, the use of specific ratios of such nutrients (alone as well as in combinations thereof) in relation to the biomass used in the composition would have been a routine matter of optimization to a person of ordinary skill in the art (As evident by the fact that the optimum amounts of sterile nutrient such as glucose, and nitrate and mineral salts are explicitly disclosed by the referenced inventions of Larsen & Joergensen, and Atlas & Parks; see discussions supra). The selection of specific ratios to be used of the nutrient components (in relation to the biomass used) in the claimed growth substrate composition clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that it is a routine procedure to optimized the ratios of ingredients for the culture of any given individual microorganism (relative to other components or nutrients used in the composition) in order to obtain an optimum yield of specific cultured product or biomass.

Furthermore, given the fact that sterile nutrients such as nitrate and mineral salts have been used by Bothe et al (in view of Larsen & Joergensen) in the cultivation of

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Methanotrophic bacteria (such as *Methylococcus capsulatus* (Bath) strain) using the composition as claimed, it would have been a matter of routine optimization of the medium composition as well as of specific ratios of the sterile nutrient in relation to the biomass used to arrive at an optimum growth substrate composition. A holding of obviousness over the cited claims is therefore clearly required.

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: *Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time this invention was made.

Response to Arguments

Applicant's arguments with respect to claims 11-14 and 25-34 (as they pertain to the rejections of record) have been considered but are moot in view of the new ground(s) of rejections presented in this office action, *supra*.

Conclusion

NO claims are allowed.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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